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EXAMINER	
ARNOLD, ERNST V	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,192	DU PLESSIS, TJAART ANDRIES	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,25-36 and 38* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21, 25-36 and 38 are pending. Claims 1-20 and 38 have been withdrawn. Claims 22-24, 37, and 39-41 have been cancelled. Claims 21 and 25-36 are presented for examination on the merits. Applicant's amendment necessitated a new grounds of rejection. Accordingly, this action is FINAL.

Comment: In claim 1, "hyaloronic" is a misspelling of hyaluronic.

Withdrawn rejections:

Applicant's amendments and arguments filed 11/30/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 21, 25, 26, 28, 35, and 36 were rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al. US 20030027883. Applicant's amendment has overcome this rejection because Phillips et al. does not expressly disclose in a single embodiment a kit with a plurality of naturally occurring biocompatible biopolymers that is irradiated after being hermetically sealed in a container.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 25-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 introduces new matter as the claim recites the limitation: "a plurality of modified naturally occurring biocompatible biopolymers". There is no support in the specification for this limitation. The limitation of: "a plurality of modified naturally occurring biocompatible biopolymers" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses "a plurality of first primary containers" in [0065] but does not describe the instantly claimed limitation. The specification discloses 'mixtures' of collagen, hyaloronic acid and demineralized bone [0030-0033] but not a "plurality" of biocompatible biopolymers. The plain and ordinary meaning of 'plurality' is: a large number or quantity. However, only 3 biocompatible biopolymers are disclosed. This is therefore a broadening of the scope and new matter. There is no guidance in the specification to select "a plurality of modified naturally occurring biocompatible biopolymers" and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor

had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 25-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites: "a plurality of modified naturally occurring biocompatible biopolymers" but then only recites collagen, hyaluronic acid and demineralised bone. How can a 'plurality', which means a large number, be merely three ingredients. Three is not a plurality. Claims 25-36 are rejected as being indefinite because they are dependent on an indefinite base claim. The claims will be examined as they read on the three biopolymers disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 25, 26, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 20030027883).

Applicant claims:

> 21. (Currently Amended) A kit for preparing and dispensing an osteoinductive agent product including a plurality of modified naturally occurring biocompatible biopolymers, the biocompatible biopolymers being selected from the group consisting of collagen, hyaloronic acid, and demineralised bone (DMB), which are first mixed and thereafter ~~was~~ subjected, in the solid, or dry state, to a source of ionising radiation in the presence of a mediating gas, the mediating gas being selected from the group consisting of acetylene, ethylene and propylene, and annealed in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form, the product being disposed in a hermetically sealed container containing oxygen-free gas and radiated again to ensure that the product is sterile.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Phillips et al. teach in claims 1-6:

1. A process for modifying a naturally occurring biocompatible biopolymer, said process comprising subjecting said biopolymer, in the solid, or dry state, to a source of ionizing radiation in the presence of a mediating gas and annealing the resulting product in the absence of oxygen at a temperature of about 40 to 120° C., and thereafter removing any residual mediating gas.

2. A process according to claim 1 wherein the source of the ionizing radiation is a γ-ray emitting radioactive isotope, X-rays or high energy radiation generated by an electron accelerator.

3. A process according to claim 2 wherein the dose of ionizing radiation to which the biopolymer is subjected to is from about 1 to 50 kGy.

4. A process according to claim 2 wherein the radioactive isotope is ^{60}Co.

5. A process according to claim 2 wherein the radiation is generated by an electron generator of 250 KeV to 10 MeV capacity.

6. A process according to claim 1 wherein the mediating gas is an unsubstituted alkenic or alkynic gas, and is ethylene, propylene or acetylene.

And in claims 9-12:

9. A process according to claim 1 wherein annealing is effected in the presence of the mediating gas, an inert gas or in vacuo.

10. A process according to claim 9 wherein the inert gas is nitrogen or helium.

11. A process according to claim 1 wherein removal of any residual mediating gas is effected by aerating the system and optionally, additionally applying vacuum.

12. A process according to claim 1 wherein the biopolymer is a polysaccharide of micro-organism, plant or animal origin, a protein of animal connective tissue origin, a protein of other animal tissue origin, a combination of at least one of said polysaccharides and at least one other protein of plant origin, or demineralized bone ("DMB")

Thus in claim 12, the combination of biopolymer polysaccharide and demineralized bone is fairly taught. In other words, a plurality of naturally occurring biocompatible biopolymers are inherently mixed when combined together to undergo the process for modifying a naturally occurring biocompatible biopolymer with ionizing radiation and are therefore modified by the process. Phillips et al. teach hyaluronan, collagen and demineralized bone as the biopolymer (claims 16, 21 and 24). Phillips et al. disclose in claims 32-36:

32. A process for modifying a tissue of animal origin, said process comprising subjecting said tissue sample or a component thereof in the solid, or dry state, to a source of ionizing radiation in the presence of a mediating gas and annealing the resulting product in the absence of oxygen at a temperature of about 40 to 120° C., and thereafter removing any residual mediating gas.

33. A process according to claim 32 wherein tissue is bone ray emitting radioactive isotope, X-rays or high energy radiation generated by an electron accelerator.

34. A process according to claim 33 wherein the bone is whole bone or demineralized bone.

35. A process according to claim 34 wherein the tissue is soft tissue.

36. A modified biopolymer produced by the process as claimed in claim 1.

Phillips et al. teach triple packaging demineralized bone which can be used to prepare and dispense the demineralized bone which is an osteoinductive agent [0147]. The packaged material, which reads on a kit, is sterilized again with 1.5 Mrad γ radiation

[0147]. Since the same process is used to treat the naturally occurring biocompatible biopolymers and packaging the product with further irradiation is also disclosed then the same product is made.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Phillips et al. is that Phillips et al. do not expressly teach a kit with a plurality of biopolymers that is radiated again to ensure that the product is sterile.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the product of Phillips et al. as a kit for preparing and dispensing an osteoinductive agent product with a plurality of biopolymers that is radiated again to ensure that the product is sterile and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is merely following the teachings of Phillips et al. who instructs the artisan to combine the biocompatible biopolymers to make the product and Phillips et al. instruct the artisan to post-sterilize the product with radiation as discussed above. Phillips et al. simply did not

disclose an embodiment with a plurality of biopolymers that were post-sterilized. The expected result is a sterile produce.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21 and 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 6610810) in view of Saito et al. (EP 0739638) and Benedict et al. (US 6679918).

Applicant claims:

> 21. (Currently Amended) A kit for preparing and dispensing an osteoinductive agent product including a plurality of modified naturally occurring biocompatible biopolymers, the biocompatible biopolymers being selected from the group consisting of collagen, hyaloronic acid, and demineralised bone (DMB), which are first mixed and thereafter ~~was~~ subjected, in the solid, or dry state, to a source of ionising radiation in the presence of a mediating gas, the mediating gas being selected from the group consisting of acetylene, ethylene and propylene, and annealed in the absence of oxygen at a temperature of from 40°C to 120°C to render the product in a dry particulate form, the product being disposed in a hermetically sealed container containing oxygen-free gas and radiated again to ensure that the product is sterile.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Phillips et al., which is Applicant's own work, teach how to modify naturally occurring biocompatible biopolymers such as collagen, hyaluronan, and demineralized

bone and combinations thereof (thus a plurality of biopolymers) in the presence of a mediating gas such as acetylene, ethylene or propylene with ionizing radiation from about 1 to 50 kGy (Abstract; column 3, lines 17-50; column 21, lines 40-63; and claims 1-53). Combinations of biopolymers are intrinsically mixed (claim 20). The product is annealed in the absence of oxygen in the presence of an inert gas such as nitrogen or helium at a temperature of about 40 to 120 C (column 4, lines 18-30; and claim 1). Phillips et al. teach in column 3, lines 50-60:

> In carrying out the process of the invention for producing the new materials from the starting biopolymers, it is preferred that the biopolymer be in its original solid state, i.e., dry, in an atmosphere comprising a mediating agent, preferably a low molecular weight unsaturated alkenic or alkynic gas such as ethylene, propylene or acetylene, preferably acetylene. Before introducing the mediating gas to the reaction site, the site must be flushed to remove therefrom any active, oxygen containing atmosphere. All the mediating gas is removed after completion of the process and therefore, the resulting new materials do not contain any of the mediating gas.

Phillips et al. teach that demineralized bone can be endowed with up to four times greater bone healing characteristics (column 26, lines 40-59; column 28, lines 5-18 and column 29, lines 13-21). Phillips et al. teach triple packaging and terminal sterilization that ensures a sterile product (column 27, lines 22-24). In the absence of evidence to the contrary, the packaging is hermetically sealed.

Saito et al. teach the concept of sterilizing pre-filled syringes (Abstract; column 5, lines 20-28 and claims 1-5). An aseptic prefilled syringe kit concept is taught (column 5, lines 29-44). Saito et al. teach using an autoclave for sterilization in claim 4 but do not

limit claim 1 to the type of sterilization process. In Figures 1-3 it can be seen that the syringe is the primary container and the package is the sealed secondary container.

Benedict et al. teach sterilization of osteogenic compositions that contain collagen, *water*, and demineralized bone material, which would include demineralized bone matrix, with ethylene oxide (column 8, lines 14-23 and claims 1, 9, 10, and 14) and by gamma radiation (claim 11). Benedict et al. teach kits of the material (column 8, lines 24-36 and claim 16). Thus, Benedict et al. establish the concept of sterilizing osteogenic kit compositions.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Phillips et al. is that Phillips et al. do not expressly teach the product as a kit for preparing and dispensing an osteoinductive agent product with a plurality of biopolymers that is radiated again to ensure that the product is sterile with an outlet opening diameter of larger than 0.6 mm on the syringe container; a second primary container containing a liquid which is pyrogen free water; disposing the secondary container inside a third hermetically sealed container which is filled with oxygen free gas; the secondary and tertiary containers are vacuum formed from a radiation stable, gas impermeable material.

2. The difference between the instant application and Phillips et al. is that Phillips et al. do not expressly teach a primary container in the form of syringe type container.

This deficiency in Phillips et al. is cured by the teachings of Saito et al. and Benedict et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have a kit for preparing and dispensing an osteoinductive agent product with a plurality of biopolymers that is radiated again to ensure that the product is sterile with an outlet opening diameter of larger than 0.6 mm on the syringe container; a second primary container containing a liquid which is pyrogen free water; disposing the secondary container inside a third hermetically sealed container which is filled with oxygen free gas; the secondary and tertiary containers are vacuum formed from a radiation stable, gas impermeable material is used on the composition of Phillips et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Phillips et al. already teach a combining the biopolymers and Phillips et al. teach a final sterilization step. It is simply following the instructions of Phillips et al. to combine the biopolymers and perform a terminal sterilization step. The size of the outlet opening and selection of container material are simply design choices by the artisan. The expected result is sterilized biopolymers in sterilized containers. It does not matter if there is one or one thousand hermetically sealed containers. The concept is already public knowledge. In the absence of evidence to the contrary, the water is pyrogen free.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a kit of the composition of Phillips et al. with a primary container in the form of syringe type container, as suggested by Saito et al. and Benedict et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art teaches a making kits of osteogenic compositions as taught by Benedict et al. and Saito et al. provide syringes for dispensing the osteogenic composition.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

The Examiner has fully considered Applicant's remarks and Declaration. The Declaration is an opinion declaration by Tjaart Du Plessis. The Declaration discusses the advantages of first mixing the biopolymers (paragraph 5) and that radiation is suited for application to plastics (paragraph 6). However, both concepts are already known in the art as discussed above. The Declaration discusses some sales of the product as well as the inventor's status with the cited Phillip's patent. Respectfully, this is not

persuasive to overcome the 35 U.S.C. 103(a) rejections above. This is an opinion declaration and the strength of the opposing evidence is overwhelming. No unexpected results have been shown. Tjaart Du Plessis is the inventor and has a great interest in the out come of the case. The Examiner notes the sale of over 5000 units and the technology license to Celtis Medzintechnologie GmbH. Essentially, Applicant is asserting that the commercial success is simply due to the product according to the claims. From MPEP 716.03(b) I: "Merely showing that there was commercial success of an article which embodied the invention is not sufficient. *Ex parte Remark*, 15 USPQ2d 1498, 1502-02 (Bd. Pat. App. & Inter. 1990)." From MPEP 716.03(b) IV: "Gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, *Ex parte Standish*, 10 USPQ2d 1454 (Bd.Pat. App. & Inter. 1988)." From MPEP 716.03(a) I: "An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. *Ex parte Standish*, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988)." For these reasons the Declaration is insufficient to overcome the rejections above.

Applicant asserts that the primary reference does not teach 'mixing' of the biopolymers. Respectfully, the Examiner cannot agree. Mixing is intrinsic to the process when more than one biopolymer is present as a combination as taught by the reference. No unexpected results have been shown. Respectfully, Applicant's arguments and Declaration are not persuasive and the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616